UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

DAVID R. LANGEVIN, Plaintiff, v. ZIMMER INC.; ZIMMER HOLDINGS, INC.; WILSON/PHILLIPS HOLDINGS, INC. a/k/a ZIMMER WILSON PHILLIPS, AND ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC., Defendants.	Case File No. _____ **COMPLAINT – JURY TRIAL DEMAND**

COMES NOW the Plaintiff, David R. Langevin ("Plaintiff"), by and through his undersigned Counsel, and for his Complaint against the Defendants, alleges as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by David R. Langevin ("Plaintiff"), as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, manufacture, distribution, and selling of Defendants' knee replacement product, the Zimmer NexGen Legacy Posterior Stabilized ("LPS") femoral component, the Zimmer NexGen Legacy Posterior Stabilized High flex ("LPS High Flex") femoral component and the NexGen MIS Stemmed Tibial component of the Zimmer NexGen total knee replacement system (hereinafter "Zimmer NexGen Knee").

2. Defendants knew or should have known that the Zimmer NexGen Knee can loosen in patients, such as Plaintiff, causing personal injury, significant pain, and loss of movement, and that this injury can only be remedied through subsequent revision surgery and/or knee replacement. Further, Defendants misled health care professionals and the public into believing that the Zimmer NexGen Knee was safe and effective for use in knee replacement surgery; engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals to utilize the Zimmer NexGen Knee, even though Defendants knew or should have known that the Zimmer NexGen Knee was unreasonably unsafe; and failed to warn health care professionals and the public about the safety risks of the Zimmer NexGen Knee.

PARTIES

3. Plaintiff is a citizen of the State of Minnesota, and a resident of Ramsey County, Minnesota.

4. Defendant ZIMMER, INC. is a corporation organized and existing under the laws of Delaware and has its principal place of business located in Warsaw, Indiana.

5. Defendant ZIMMER HOLDINGS, INC. is a corporation organized and existing under the laws of Delaware and its principal place of business is located in Warsaw, Indiana.

6. Defendant WILSON/PHILLIPS HOLDINGS. INC. A/K/A ZIMMER WILSON PHILLIPS is a corporation organized and existing under the laws of Texas and has its principal place of business in Richardson, Texas.

7. Defendant ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC. is a corporation organized and existing under the laws of Ohio and has its principal place of business in Dover, Ohio.

8. At all times material hereto, Defendants developed, designed, tested, manufactured, distributed, marketed and sold the Zimmer NexGen Knee. Defendants' products, including the Zimmer NexGen Knee, are sold throughout the world, including within the state of Minnesota.

JURISDICTION AND VENUE

9. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

10. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(a), as a substantial number of the events, actions or omissions giving rise to Plaintiff's claims occurred in this district. At all times material hereto, Defendants conducted substantial business in this district.

FACTUAL BACKGROUND
KNEE REPLACEMENT BACKGROUND

11. Total knee arthroplasty (TKA), commonly referred to as "total knee replacement," is a common medical procedure. The surgery is designed to help relieve pain and improve joint function in people with severe knee degeneration due to arthritis and/or trauma.

12. Upon information and belief, the TKA procedure is done by separating the muscles and ligaments around the knee to expose the inside of the joint. The ends of the thigh bone (femur) and the shin bone (tibia) are removed as is often the underside of the kneecap (patella).

13. Upon information and belief, about 85 to 90 percent of total knee replacements are successful up to ten years.

14. Mechanical loosening means that for some reason (other than infection) the attachment between the artificial knee and the bone has become loose.

15. Loosening can occur with any component of the artificial knee: the femoral, the tibial or the patellar component.

16. Upon information and belief, loosening of an artificial knee can be diagnosed using X-ray. In x-ray pictures of a loose knee joint there are one or more radiolucent lines around the contours of the artificial knee joint.

17. A loose artificial knee is a problem because it causes pain and wearing away of the bone. A painful loose knee can restrict the patient's daily activities severely. A loose artificial knee also involves severe psychical burden for the patient.

1 8. Once the pain becomes unbearable or the individual loses function of the knee, another operation will probably be required to revise the knee replacement. A loose, painful artificial knee can usually, but not always, be replaced.

19. The purpose of knee revision surgery is to remove a failed knee implant and replace it with a new one.

20. Upon information and belief, in a revision of a TKA because of loosening and/or failure, the biggest concern is usually the problems associated with severe bone loss caused by bone destruction around the failed total knee prosthesis when attempting to restore the stability in the revised total knee.

21 . Upon information and belief, the results of a revision operation are not as good as the first, and the risks of complications are higher. The range of motion in the knee after the revision surgery may be smaller and the walking capacity may be also diminished. The rate of loosening is higher after revision surgery than in primary knee replacement surgery.

ZIMMER NEXGEN KNEE FACTS

22. Zimmer was founded in 1927, and purports to be a worldwide leader in the design and manufacture of orthopaedic reconstructive, spinal and trauma devices, dental implants, and related orthopaedic surgical products.

23. The Zimmer NexGen Knee uses a “high-flex” femoral component that purports to allow a greater degree of flexion than the standard femoral component.

24. The Zimmer NexGen Knee also uses a stemmed tibial component that is designed to be assembled within the patient thereby allowing for minimally invasive surgery techniques.

25. The Defendants generally, manufactured, labeled, packaged, distributed, supplied, marketed, advertised and/or otherwise engaged in all activities that are part and parcel of the sale and distribution or a pharmaceutical, and by said activities, caused the Zimmer NexGen Knee to be placed into the stream of commerce throughout the United States.

26. Defendants made, participated in and/or contributed to filings with the FDA in conjunction with the approval process for the Zimmer NexGen Knee.

27. Upon information and belief Defendants was in control of the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion, sales, and the issuance of product warnings and related information with respect to the Zimmer NexGen Knee.

28. Defendants were at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof, in conjunction with the approval process, labeling, and other aftermarket activities that pertain to the Zimmer NexGen Knee.

29. The Zimmer NexGen Knee has been widely advertised, marketed and represented by the Defendants as a safe and effective treatment.

ZIMMER NEXGEN KNEE PROBLEMS

30. In 2007, The Journal of Bone and Joint Surgery (British Edition), published a peer reviewed study by professors at the Seoul National University College of Medicine titled, *High Incidence of Loosening of the Femoral Component in the Legacy Posterior Stabilised-Flex Total Knee Replacement.* The study showed that 38% of the implanted LPS high flex knees were loose shortly after 2 years post implant. From the group of patients with loose knees, over half (56%) had their knee revised due to pain.

31. In March 2010, Dr. Steven Weeden, of the Texas Hip and Knee Center, was a speaker at a national meeting of the American Association of Orthopedic Surgeons regarding a study reporting a higher than expected rate of early loosening in cemented primary total knee replacements when a MIS tibial component was used without an additional modular stem. In the MIS tibial components placed without an additional modular stem, the failure rate was 24% versus 4.2% with a stem.

32. On or around April 2010, Defendants sent an "Urgent Device Correction" letter to all customers using the MIS stemmed tibial components. In that letter, Defendants advised customers of a change in labeling and recommended usage of the MIS stemmed tibial component:

> Zimmer is enhancing the labeling for the NexGen MIS Tibial Component in several important ways. The changes to the labeling include the following recommendations:
>
> 1. to achieve adequate visualization and access if a MIS approach is used,
> 2. to use a drop down stem extension with the NexGen MIS Tibial Component,
> 3. to fully cement and pressurize the anterior and posterior surfaces of the tibial component, and;
> 4. to carefully use bone cement application per the manufacturer's instructions.

33. On September 13, 2010, the FDA classified the Defendants efforts relating to the MIS stemmed tibial components as a Class II Recall.

34. From the time that Defendants first began selling the Zimmer NexGen Knee in the United States, the product labeling and product information for the Zimmer NexGen Knee failed to contain adequate information, instructions, and warnings concerning implantation of the product and the increased risks that the Zimmer NexGen Knee can loosen in patients.

35. Despite its knowledge of the serious injuries associated with use of the Zimmer NexGen Knee, Defendants engaged in a marketing and advertising program which as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the Zimmer NexGen Knee was safe.

36. Upon information and belief, Defendants downplayed and understated the health hazards and risks associated with the use of the Zimmer NexGen Knee and through promotional literature as well as sales visits to orthopaedic surgeons, deceived doctors and potential users of the Zimmer NexGen Knee by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

FACTUAL ALLEGATIONS

37. On or about May 25, 2005, Plaintiff's physician implanted a Zimmer NexGen Knee system including a NexGen LPS High Flex femoral component and a MIS stemmed tibial component.

38. Prior to the surgical date of May 25, 2005, the treating physician for Plaintiff, as well as Plaintiff, were exposed to the aforementioned advertising and marketing campaign directly by the Defendants.

39. Plaintiff and Plaintiff's physician, either through direct promotional contact with Sales Representative Defendants, through word-of-mouth other healthcare providers, and/or through promotional materials, received the information the Defendants intended Plaintiff and Plaintiff's physician to view, to wit: that the Zimmer NexGen Knee was safe and effective for use in TKA procedures.

40. Plaintiff began experiencing severe and debilitating pain shortly after implant.

41. Plaintiff returned to Plaintiff's physician several times due to consistent pain relating to his Zimmer NexGen Knee and in 2010 was advised that his Zimmer NexGen Knee was experiencing "loosening" and would need to be revised.

42. As a direct and proximate result of the use of the Zimmer NexGen Knee, Plaintiff suffered, and continues to suffer, serious bodily injury and harm.

44. As a direct and proximate result of the use of the Zimmer NexGen Knee, Plaintiff incurred, and continues to incur, medical expenses to treat his injuries and condition.

45. At no time material to his use of the Zimmer NexGen Knee was Plaintiff or his physicians told, warned, or given information about the higher risks of loosening in the Zimmer NexGen Knee.

COUNT I
NEGLIGENCE

79. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further states and alleges as follows:

80. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of Zimmer NexGen Knee, including a duty to ensure that Zimmer NexGen Knee did not pose a significantly increased risk of bodily injury to its users.

81. Defendants had a duty to exercise reasonable care in the advertising and sale of Zimmer NexGen Knee, including a duty to warn Plaintiff and other consumers, of the dangers associated with the consumption of Zimmer NexGen Knee that were known or should have been known to Defendants at the time of the sale of Zimmer NexGen Knee to the Plaintiff.

82. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of Zimmer NexGen Knee because Defendants knew or should have known that Zimmer NexGen Knee had a propensity to cause serious injury, including loosening and revision surgery.

83. Defendants failed to exercise ordinary care in the labeling of Zimmer NexGen Knee and failed to issue adequate pre-marketing or post-marketing warnings to prescribing doctors and the general public regarding the risk of serious injury, including, loosening and revision surgery.

84. Defendants knew or should have known Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

85. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

86. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer NexGen Knee. Plaintiff was implanted with Zimmer NexGen Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

87. WHEREFORE, Plaintiff demand judgment against Defendants for compensatory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all his injuries and damages, both past and present;

2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of his injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.

3. Attorneys' fees, expenses, and costs of this action;

4. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

5. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff specifically demands a trial by jury of all claims asserted in this Complaint.

MCSWEENEY & FAY, P.L.L.P.

Dated: April 19, 2011

/s/ David M. Langevin

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